RFP-NIH-NIAID-DMID-08-04

Amendment 2 (Questions and Answers, 1st Posting)

This Amendment provides questions submitted by potential offerors and the responses provided by the NIAID. This Amendment will be updated as necessary to add any further questions and their related responses. All potential offerors are advised to refer back to this Amendment every two weeks to check for additional Questions &Answers.

"Statistical and Data Coordinating Center (SDCC) for Clinical Research in Infectious Diseases"

Amendment Issue Date:	04/04/2007
Proposal Due Date/Time: (UNCHANGED)	05/14/2007 at 3:00 P.M., EST
Issued By/Point of Contact: (UNCHANGED)	Deborah A. Baca Contract Specialist OA/DEA/NIAID/NIH/DHHS 6700-B Rockledge Drive, Room 3214, Bethesda, Maryland 20892-7612 dbaca@niaid.nih.gov **Please also cc:** baughmat@niaid.nih.gov Terry Baughman, Contracting Officer

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Offerors must acknowledge receipt of each posting of this Amendment 2, on each copy of the proposal submitted. Failure to receive your acknowledgment of this Amendment may result in the rejection of your proposal.

The hour and date specified for receipt of proposals HAS NOT been extended.

April 27, 2007, 4:00 P.M. EST WILL BE THE LAST DAY QUESTIONS REGARDING THIS RFP WILL BE ACCEPTED.

THE FOLLOWING PAGES PROVIDE ANSWERS CONCERNING INQUIRIES WE RECEIVED FOR THE ABOVE-NUMBERED SOLICITATION:

Question 1: Page 5 of the solicitation states, "studies to be supported shall be conducted within and outside of the United States." Does this mean that contractor employees will be required to travel to International locations in performance of this work? If so, does the Government expect that contractor employees will perform in International locations for short-terms or long-term periods? Please advise.

Question 2: Attachment 6, Page 4: In which countries are the foreign clinical sites located?

Question 3: Will the same clinical sites be utilized over the course of the contract?

Response 1, 2 and 3: See Attachment 6, Additional Business Proposal Instructions, Page 4, Section 2 for uniform cost assumptions to be used in preparation of your cost proposal regarding meetings and travel to domestic and foreign clinic sites. The foreign countries and clinic sites will vary depending on the studies being conducted.

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Question 4: Where will the clinical sites be located in the U.S.?

Response 4: To be determined. Also, see Attachment 8, DMID Clinical Research Contracts, for a partial listing of current sites.

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Question 5: Will the clinical sites, both domestic and foreign, be chosen by DMID?

Response 5: Yes, the clinic sites will be chosen by DMID.

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Question 6: Attachment 3, Item 1.b.11 requires that "For a site with unreliable electrical power, implement alternate power source, back-up systems and/or contingency plans." This requirement has substantial budget implications, particularly for international sites. How many such sites should we anticipate in budgeting equipment for such scenarios, and where are those sites expected to be located?

Question 7: Attachment 3, Item 1.b.10 requires that "For a site with intermittent internet connection, provide a system for off-line data entry. Data may be transmitted at a later time when internet connection is available." Our assumption is that the Institute expects that some form of distributed system that provides a local data entry system with batch upload. Our experience is that such systems are very difficult to validate to 21 CFR Part 11 standards (another requirement of the RFP) without the use of dedicated computers. Should the SDCC budget include provision of such computers, and if so, how many such sites should we anticipate?

Response 6 and 7: Procurement of necessary hardware on the site level will not be the responsibility of the SDCC. DMID will purchase any equipment required by the sites. Also see Attachment 5, Additional Technical Proposal Instructions, page 6-7, Section 5.A.5.

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Question 8: Attachment 3, page 7, Item 4.b.1.g requires that the SDCC "Plan specific aspects of site monitoring visits and, where appropriate, identify, verify and recommend remedies to address deficiencies identified during data submission (e.g. numerous protocol deviations) or during previous site visits (e.g., selecting computerized data elements to be verified); provide data entry screens for the clinical site monitors to document their record review and provide a status update of monitoring progress for each study at each participating study site;" We assume that this requirement means that the clinical trial management system that the monitors use for their data reporting will be developed, maintained and controlled by the SDCC rather than the CTM contractor. Is that correct?

Response 8: The clinical monitors will utilize the SDCC system required in Attachment 3, Statement of Work page 3, Section 1.

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Question 9: Page 11 of the SOW describes the requirements for Initial and Final Transitions. Does "contract-generated materials" include the incumbent's database and code, or will the new Contractor be expected to design their own database and code?

Response 9: The database being used by the current contractor is proprietary and will not be provided to the new contractor. Attachment 5, page 2, Section 2.B. provides information on the features for the offerors' proposed computer-based systems..

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Question 10: Attachment 3, page 12 says that we will deliver data entry software (assume the EDC and other systems), at the end of the contract. Is such a requirement embedded in the current contract and should we anticipate that we will provided with the current EDC system to facilitate transition at the sites between the current and new systems should a new vendor be selected?

Question 11: What Electronic Data Capture (EDC) system is the EMMES Corporation currently operating with? Is this a proprietary or commercially available system? If a proprietary system, will this be available to the new contractor to assist in the transition of the project?

Response 10 and 11: The data entry software (EDC) being used by the current contractor is proprietary and will not be provided to the new contractor.

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Question 12: Are there existing templates in place for study-related materials that can be used by the new contractor or will these need to be created for all new clinical trials?

Response 12: Some existing written documentation will be provided to the new contractor; however, as stated in Attachment 3, page 5, Section 2., the contractor will be required to prepare new materials as well.

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Question 13: Page 5 of the solicitation under Article B.4 states that subcontracts must be approved by the Contracting Officer before incurrence of the cost. If the contractor's proposal includes proposed subcontractor costs, does the acceptance of the contractor's proposal by the Government automatically include the acceptance of the subcontract costs? Please advise.

Response 13: No, all subcontractor costs are subject to negotiations and require prior written approval by the Contracting Officer. Award of the prime contract may not automatically include approval of proposed subcontracts depending on the outcome of the negotiations.

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Question 14: Page 13 of the solicitation under Article H.6.d states, "the contractor shall ensure that each contractor/subcontractor employee has completed the NIH Computer Security Awareness Training course." Is there a cost to enroll and complete this course? If so, will the Government please state the cost?

Response 14: This is an on-line course available free of charge. Refer to Article H.6.d of the RFP for the website.

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Question 15: Amendment #1 changes the overall level of security required to Moderate. Due to this change, please verify that the contractor employees are still only required to meet the Level 1: Non Sensitive requirements? If employees are required to meet requirements other than Level 1, please define the employee categories under the contract that must meet Level 5 or 6 determinations?

Response 15: Please refer to RFP Amendment 3 which addresses this question and changes the position sensitivity designation.

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Question 16: Do the Contractor employees need to be American citizens or legal residents to meet Level 1, 5 or 6 requirements?

Response 16: American citizens are eligible to apply for security clearance for Levels 1,5 and 6. Eligibility for clearances of all other individuals is determined on a case by case basis.

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Question 17: We have previously prepared an ISSP using the NIST template, but we are unsure of where to locate information on the exact difference between the ISSP and the SSP. Can the Institute provide clarification?

Response 17: Please refer to Amendment 3 which addresses this issue.

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Question 18: Attachment 5, page 3, paragraph A.11., suggests that the offeror include in the technical proposal the AIS, SSP, and COOP. Attachment 3, page 4, indicates that the SSP should include the COOP and RA. Is the SSP in addition to the ISSP and the draft self assessment questionnaire? Are all of these documents to be included in the 200-page limit?

Question 19: In the Technical Proposal Instructions, page 40 of the RFP, Paragraph b.5 (f) requires that the offeror include in the technical proposal a completed Self-Assessment Questionnaire as required by NIST Draft 800-26, Revision 1. Paragraph b.5 (g) on page 40 requires that the offeror include in the technical proposal a draft ISSP using the current template in Appendix A of NIST 800-18. Are these required documents included in the 200-page limit placed on the technical proposal?

Response 18 and 19: Please refer to Amendment 3 which addresses this issue. In addition, refer to Attachment 5 which states, "Offerors are reminded that the total page limitation for the entire technical proposal package is 200 pages inclusive of all attachments and appendices."

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Question 20: Page 13 states that "upon the receipt of the Government's notification of applicable Suitability Investigations is required, the contractor shall complete and submit the required forms within 30 days of the notification." Is the Contractor required to submit all suitability investigation forms within 30 calendar days or 30 business days of the notification of award? Please advise.

Response 20: The Contractor is required to submit all suitability investigation forms within 30 calendar days of the notification of award.

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Question 21: RFP Page 38, Item #5: Please clarify whether the 'Information Security' Section can be a subsection of Section 3, or whether it must be an independent section unto itself. (IMPORTANT NOTE TO OFFERERS)

Response 21: Page 38 of the RFP states, "The following information shall be addressed in a separate section of the Technical Proposal entitled, INFORMATION SECURITY."

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Question 22: Article H.7 on page 14 of the RFP expresses the requirement for a NARA-compliant records storage facility. Can you please provide an estimate of the volume of records currently being maintained under the contract held by Emmes Corporation and the location of the storage facility? We assume that responsibility for maintenance of these records will be transferred to the successful bidder on the subject RFP and that any costs for transferring the existing records to a new storage facility should be included in our bid.

Response 22: Per Amendment 1 to this RFP, Article H.7. was deleted in its entirety.

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Question 23: Page 10 of the SOW defines the requirements for "Data Storage." Will the Government please estimate the percentage (if any) of the data to be stored in the data storage facility will be provided to the contractor in paper format? Will the Contractor be expected to convert data that is supplied in paper format to an electronic format in order to provide access to the data electronically? Or will they simply provide a facility to store paper and/or electronic files for the Government?

Response 23: All data will be provided in Electronic Format.

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Question 24: The RFP specifies that the contract initiation meeting may take place as much as 60 calendar days after effective date of contract (Attachment 3, page 10), but many of the deadlines for other early project deliverables (e.g., set-up of webpages, training modules, data entry system) are anchored by the effective date of contract rather than on the initiation meeting date. Should we anticipate a series of teleconferences or other meetings with DMID and the current contractor prior to the formal initiation meeting to address the inevitable issues that will need to be addressed to allow a relatively painless transition of materials and to facilitate development of compatible web and data systems? Alternatively, would the Institute recommend anchoring some of the deliverable dates to the timing of the initiation meeting date?

Response 24: No, do not anticipate a series of teleconferences or other meetings with DMID and the current contractor prior to the formal initiation meeting to address inevitable issues, etc. RFP Attachment 3, page 10, item 10. b.1) states "…within 60 calendar days after the effective date of the contract, participate in a one-day Contract Initiation Meeting with the Project Officer, to be held at the Contractor's site." The timing could be any time prior to 60 calendar days, even as early as a week or two after the effective date of the contract. The actual date will be agreed upon by the Contractor and the Project Officer.

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Question 25: The Additional Technical Approach Instructions indicate that the computer-based systems should be "equivalent or comparable" to one of four platform/systems. However, we find no such equivalence requirement explicitly stated in the Technical Evaluation Criteria leading to three questions. First, is the demonstration of equivalence a requirement on which proposals will be evaluated (the absence of any Technical Evaluation Criteria on point leads us to ask this question)? Second, if proposals will be evaluated on this criterion, can the Institute please provide the criteria by which it plans to evaluate equivalence or comparability, since equivalence and comparability are substantially different standards, particularly in discussing compliance with 21 CFR Part 11. Third, the list of platform/systems includes both general platforms and specific systems. If comparability/equivalence is to be demonstrated, is it for both the general platform (Oracle) and one of the 3 specific systems, or is only comparability with any system that sets on an Oracle platform required?

Response 25: Please refer to Amendment 3 which addresses this issue and deletes the wording "equivalent or comparable". In addition, see RFP, page 52, CRITERION 3 which discusses the evaluation criteria for how equipment and facilities will be evaluated. It is up to the offeror to decide the system platform to propose.

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Question 26: On page 50 of the RFP, item 1 under Criterion 1 indicates that one point related to the evaluation of Data Collection, Management, and Quality Control will be the adequacy and feasibility of plans and procedures for "halting rules requirements." Our experience is that plans and procedures related to halting rules requirements is a statistical, not a data management issue. Is this evaluation criterion actually related to the halting rules requirements or to the ability of the data system to track the study progress relative to reaching those requirements?

Response 26: For additional clarification, see Attachment 5, Section 3.A.5.
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Question 27: Page 50 of the Solicitation states that the technical approach shall include an explanation of the contractor's "ability to collect, manage, and control the quality of clinical and laboratory data as evidenced by the soundness…" Will the Government please provide examples of existing records (*i.e.* the characteristics of the lab research data and data elements contained in the records) to the Contractor?

Response 27: The Government will not be providing examples of existing records; however clinical and laboratory data will vary depending on each protocol. It may include but is not limited to: alpha, numeric, and some graphics. For additional clarification, see Attachment 5, Section 3. Also, see Attachment 3, page 3, Sections 1.a., and 1.b.3) and Section 4); and page 5, Section 3.a.2).

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Question 28: On page 50 of the RFP, item 3 under Criterion 1 contains the phrase "plans for the number and content of each web-site." We are uncertain what the Institute means by the phrase "number . . . of each web-site."

Response 28: See Attachment 6, Additional Business Proposal Instructions and Uniform Budget Assumptions, Section 3, items 1.a.4) and 1.b.6). In addition, see Attachment 3, page 5, Section 3.

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Question 29: Page 51 describes the requirements for Statistical Design and Analysis. Will the Government please quantify the approximate number of statistical designs and analyses the Contractor will be expected to perform per year?

Question 30: Page 7 of the SOW under part 5 defines the statistical design requirements. Will the Government please estimate the number of statistical designs to be created per year?

Question 31: Page 8 of the SOW under part 5 defines the statistical analyses requirements. Will the Government please estimate the number of statistical analyses to be completed per year?

Response 29, 30 and 31: See Attachment 6,Section 3, item .a.1) (Clinical Trials) and Section 3, item,1.b) 6) (Scope of SDCC Support).

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Question 32: Page 8 of the SOW defines the requirements for Pre-publication/presentation analyses and states that the contractor will be required "prior to presentation or submission for publication, review for accuracy all abstracts, manuscripts, and presentations…" Will the Government please provide an estimate of the number of manuscripts the contractor will be required to review per year?

Response 32: See response to questions 29, 30, and 31 above.

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Question 33: How many DSMBs provide oversight for the various DMID trials (Attachment 6, page 2 only states that there are 40 Safety Oversight Structures requiring reports at various frequencies each year)? Will there be face-to-face or teleconferences that a reporting statistician/DSMB coordinator will be required to attend? If so, what is the frequency and what is the SDCCs responsibility for organizing and documenting SOS meetings?

Question 34: In Attachment 3 page 8, the SDCC is responsible for preparing and presenting statistical designs and plans for interactions with the FDA. Does this require travel to the FDA? Approximately how many FDA meetings are anticipated over the course of the contract?

Response 33 and 34: As clarification, the Safety Oversight Structures' meetings are convened via teleconference. On rare occasion, a face-to-face meeting may be held. Attachment 3 does not state that the SDCC is responsible for the coordination or documentation of Safety Oversight Structures' meetings. For additional information, See Attachment 3, Section 5. FDA is considered one of the "Safety Oversight Structures" referred to in Attachment 6, page 2, Section 3, item 1.a.5). Any travel assumptions are listed in Attachment 6, Section 3, item 2.

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Question 35: In Attachment 3, page 1, the RFP states that studies may focus on emerging infectious disease pathogens and pathogens that are potential agents of bioterrorism. Moreover, in the background section of Attachment 3 (page 1), the RFP states that the SDCC will provide support for targeted surveillance for specific pathogens in the study populations. However, the RFP has no corresponding reference to development or implementation for statistical design and analysis methods that would be appropriate for such surveillance programs. Because the challenges and solutions to implementing targeted surveillance programs are quite different from those associated with clinical trials (e.g., special sample frames may need to be developed and subject-level rather than site-level data collection tools may be needed), does NIAID have any guidance relating to the responsibilities of the SDCC in supporting such studies?

Response 35: Attachment 3 does not state that SDCC will provide the support. The background section of the RFP is referring to the overall mission of DMID and the studies DMID supports, not what this contractor will be supporting under this contract. The information on what the contractor will support is included in the Statement of Work.

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Question 36: On page 6 of Attachment 3 and page 4 of Attachment 5 in the RFP, information on coordination processes with DMID staff and clinical research support services contractors is requested. Is the SDCC responsible for coordinating meetings among the various contractors, including arranging calls, developing agendas and documenting meeting decisions? Are existing SOPs for these processes available that could be modified?

Response 36: Attachment 3, page 6, Section 4.b.1 discusses for the Contractor's coordination and collaboration requirements. There are no SOPs for coordination and collaboration.

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Question 37: Will the Government please define the meaning of "source documents" in the context it is written on Page 5, Part 3, of attachment 3 (SOW)?

Question 38: In Attachment 3 page 5, the contractor is requested to provide access to source documents through the website. In this context does the term 'source documents' refer to worksheets or templates that can be used by the site to construct source documents or are you suggesting that something like scanned versions of actual source documents should be available on the website for use in central monitoring? If the latter, we have concerns about HIPAA issues.

Response 37 and 38: Attachment 3, Section 3 a.2)f) refers to study specific blank source document worksheets or data collection tools or forms to be used by the site. Please also see ICH E6 GCP guidance, definition 1.52.

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Question 39: Is the Contractor expected to prepare (from the list of study-specific materials contained on page 5, part 3, of the SOW) protocol and protocol amendments; consent forms; investigator brochures and/or package inserts; or logs of frequently asked questions with answers, or will these items be provided by the Government as ready for posting by the Contractor to the website? Please advise.

Question 40: In Attachment 3 page 7, the SDCC is responsible for reviewing successive versions of protocols and providing recommendations on statistical design issues. In other parts of the RFP, such as Attachment 6 page 3, the SDCC is responsible for development of study related materials. Is the SDCC responsible for overseeing the development of protocols, including organizing protocol development meetings, documenting decisions made, protocol formatting, incorporating edits and working with the Project Officer to obtain approvals of a final version, or can we expect that the SDCC will be provided with a fully complete protocol that will be used to develop all other study documents?

Response 39 and 40: Attachment 3, page 5, Section 2.a., states, "The Contractor shall prepare materials for the implementation of clinical trials and clinical studies". This refers to the types of study-specific materials that may be required to be prepared and posted on the clinical study website. Certain items are listed, but the list is not all inclusive of what might be required to be prepared by the Contractor. It also states, "Draft materials will be reviewed by the Project Officer…..and revised as necessary to incorporate recommended modifications." Therefore, Contractor will be responsible for preparation of revisions to documents to incorporate modifications as necessary.

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Question 41: We have concerns about inconsistencies between the Statement of Work, the Evaluation Criteria, and the Additional Technical Proposal Instructions in Attachment 5 regarding the scope of statistical design and analysis support. Both the Statement of Work and the Evaluation Criteria indicate that the SDCC will be required to support trials related to a wide array of vaccines and therapeutics. However, the Additional Technical Proposal Instructions in Attachment 5 only provide for addressing vaccine trials. Obviously the scope of statistical methods and associated outcome measures for the wide range of therapeutics outlined in the Statement of Work differs substantially from the scope of those methods and outcomes for only vaccine trials. Is the broader scope as outlined in the SOW and Evaluation Criteria correct, or will the proposal be expected to only address vaccines as specified in the Additional Technical Proposal Instructions?

Response 41: Please refer to Amendment 3 which addresses this issue.

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Question 42: Referring to page 5 of the SOW, are the test article accountability logs listed in 2.a. the same as the tracking and dispensing logs listed in 3.a.2.h? If not, will the Government please explain why they differ?

Response 42: Accountability logs listed in Attachment 3, Section 2. a. is a general reference to test article accountability documentation. Section 3. a.2.h) is more descriptive in the use of the terms 'tracking and dispensing logs.' Essentially, tracking and dispensing are the activities related to maintaining accountability logs.

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Question 43: Page 9 of the SOW states the contractor will be required to "establish and maintain a 24 hour/7-day per week telephone help line". Does the telephone help line need to be manned by an actual person 24/7 or can recordings of requests for information be made between, 11 PM and 7 AM (for example) and answered the next day?

Response 43: Yes, the hotline needs to be maintained 24/7 by an actual person to provide a timely response to requests for information or assistance.

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Question 44: Page 9 of the SOW defines the requirements for the Electronic Specimen Tracking System. Will the Government please estimate the number of electronic specimens the contractor will be required to track per year? The contractor is aware that this question is partially answered in Attachment 6, page 3 as specimens per subject. However, it is not stated how many subjects are expected to enroll in the Phase I and II clinical trials. Please advise.

Question 45: How many subjects should the Contractor assume will be enrolled in Phase I and II trials, for which the clinical specimens are being collected?

Response 44 and 45: Please refer to Amendment 3 which addresses this issue.

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Question 46: Please clarify as to whether data from the electronic specimen tracking system needs to be integrated into the electronic data capture system?

Response 46: Attachment 3, page 9, Section 7.a.1. states that the electronic specimen tracking system shall have, "integration with the clinical data management system."

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Question 47: Page 9 of the SOW under the section titled Electronic Specimen Tracking System states, "contractor shall design, implement, operate, and update an Electronic Specimen Tracking System…" Please clarify as to whether the new Contractor will be expected to create a new tracking system, or will be expected to modify the existing incumbent's tracking system? Please advise.

Question 48: Will the current electronic specimen tracking system be available to the new contractor for review or use during the transition period?

Response 47 and 48: See Attachment 3, page 9, Section 7.a. which states, "The Contractor shall design…an electronic specimen tracking system…" The incumbent's existing tracking system will not be provided to the new contractor.

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Question 49: Attachment 3, Item 3.a.4 requires: "The provision of real-time access to study data by site and total overall, including accrual, adverse event and serious adverse event listings, protocol deviations, specimen tracking and inventory, missing forms, visit schedule compliance, data queries and progress monitoring information/materials." By "real-time access to study data" is the Institute expecting that the system will be able to dynamically generate any report encompassed by these requirements in real-time or simply requiring that a plan be available to generate reports periodically (with periods possibly ranging from daily to monthly, depending on the data and study) and that these static reports be available on the web-site?

Response 49: Yes, the system must be dynamic allowing web-based access to study data reports that are generated real-time.

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Question 50: Please confirm whether the EDC system should also be available for intermittent off line use by the clinical sites.

Question 51: Please confirm whether the EDC system should also be available for complete off line use by the clinical sites.

Response 50 and 51: Attachment 3, Section 1 a., states,, "The Contractor shall make other accommodations for data entry by a small number of study sites with questionable computer capability and/or internet connection." Section 1 b.10) states, "For a site with intermittent internet connection, provide a system for off-line data entry. Data may be transmitted at a later time when internet connection is available."

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Question 52: In Attachment 3 page 6, pharmacovigilance data are to be reconciled with data from the clinical database. Will data be transferred electronically, and how frequently are data transfers planned and data reconciliation for a study required?

Response 52: Yes, the data will be transmitted electronically and on an as needed basis.

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Question 53: Page 4 of Attachment 5 under section C, states that the contractor shall describe plans for "assessing compliance with randomization and appropriate administration of test articles." Will the Government please provide examples of the "test articles"?

Response 53: A test article is any intervention given to a study subject. Examples include drugs, biologics and devices.

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Question 54: Page 6 of Attachment 5 states that "the Government estimates the effort for the Principal Investigator to be approximately 75%." Will the Government please describe the rationale for limiting the Principal Investigator to a 75% effort?

Response 54: This is not limiting, it is an estimate. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

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Question 55: Page 6 of Attachment 5 states that the contractor will be required to "describe the education, training, experience, expertise, qualifications of key personnel". Will the Government please provide further information as to the minimum personnel qualifications, i.e. degrees, years of experience, education, etc?

Question 56: Will the Government please provide the approximate number of statisticians, research staff, systems analysts, and programming and information technology professionals that are performing under the current contract?

Question 57: Section 5 on pages 6 and 7 of Attachment 5 states that the contractor shall, "provide a description and documentation of the availability and adequacy of facilities, equipment and other resources to be used for performance of the contract…" Does the Contractor have to show proof of ownership of the equipment required to administer this contract, or will evidence as to how it will be acquired upon winning the contract be sufficient?

Response 55, 56, and 57: Each offeror has to decide how best to present their proposed personnel's qualifications and capabilities and how to cost out their business proposal (including labor hours/effort) based on how they propose to do the work outlined in the Statement of Work, Attachment 3. The business proposal should include costs based on how an offeror proposes to perform the work, and also in accordance with the uniform cost assumptions included in Attachment 6. Also, each offeror has to determine how best to document the availability of the facilities, equipment and other resources they propose.

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Question 58: Do the information docs referred to on page 22 of the RFP need to be completed and submitted with the proposal on 14 May 2007?

Response 58: No. Section J of the RFP states that these are "Informational Documents", that they will become attachments to any contract resulting from this RFP, and will be required during contract performance.

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Question 59: Please clarify whether the assumptions for b) Site assessments; c) study initiations and d) study site visits (Attachment 6, page 4), refer to training visits as specified in Task 6 "Clinical Site Training, Assessment and technical Assistance" (Attachment 3, page 8) or monitoring of the data.

Response 59: Yes, Attachment 6, Section 3, items 2. b), c), d) and e) refer to activities described in Attachment 3, Section 6. Clinical Site Training, Assessment and Technical Assistance.

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Question 60: Is there a cut-off day for submission of questions regarding this RFP?

Response 60: Final cut-off day for questions regarding this RFP is April 27, 2007 at 4:00 p.m. EST.

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